

### Advanced Safe Testing at Residence Telehealth Act of 2021

Supporting Americans and Innovation through Safe Remote Testing and Telehealth

- Numerous studies on telehealth have shown benefits for providing quality evidence-based health care, access to care, early intervention, reduction in acute episodes, and reduced spending.
- At-home healthcare has been a vital tool in the fight against coronavirus. Innovative diagnostics will accurately diagnose disease states and conditions quickly, conveniently, and affordably.
- Future technology will provide practitioners and patients with the time, resources, and data needed to make more informed decisions about primary care and chronic disease management.

The Advanced Safe Testing at Residence Telehealth Act of 2021 (A-START) would expand patient and provider access to healthcare innovation to promote higher quality and increased access to 21<sup>st</sup> century, technology-based care. It consists of three demonstration pilots designed to explore the improved capabilities of telehealth, diagnostics, screening, and patient monitoring technology.

### **A-START Act of 2021 Summary**

Sec. 1 – Short title; Table of contents

### Sec. 2 – Medicare Advantage Demonstration Program; State Medicaid Demonstration Program

# (a) Medicare Advantage Demonstration Program

- (a) Establishes Value-Based Insurance Design Model 'VBID demonstration program.'
  - (1) Allows for telehealth consultation for practitioner and beneficiary not in the same location.
  - (2) Clarifies eligible MA organizations that the Secretary shall enter into agreements.
  - (3) Limits the number MA plans to 25, with 10 representing rural or underserved areas.
  - (4) Defines eligible MA plans to be ones that provide certain coverage (see: *Tests Covered*).
  - (5) Telehealth visit and tests under (4) are subject to documentation and claims review.
  - (6) Requires certain demographic data collection for claim reimbursement.
  - (7) Defines the term 'assistive telehealth consultation' as a telehealth service.
- (b) Defines state and eligibility for MA organizations to participate in VBID demonstration program.
- (c) Defines eligible Medicare beneficiary requirements.
- (d) Establishes payment rates under VBID to be based upon rates under section 1853 (MA).
- (e) Provides special enrollment period for beneficiary to elect a new MA plan participating in VBID.
- (f) Requires additional education is provided for organizations assisting with benefits and enrollment.
- (g) Program shall begin no later than January 1 of the second year after enactment and run five years with option to extend or expand program should the Secretary determine it meets criteria.
- (h) Requires independent evaluation and reports to determine if the program meets its outlined goals.
- (i) Requires any year after the third year or program to be budget neutral.
- (i) Removes paperwork reduction act requirement.

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## (b) State Medicaid Demonstration Program.

- (1) Establishes not later than 1 year a 5 to 10 state or territory Medicaid grant program to provide coverage for individuals under the state plan for (see: *Tests Covered*).
- (2) Requires State to submit application containing information as the Secretary requests.
- (3) Authorizes the grant for a 4-year period not to exceed \$12,000,000 per state.
- (4) Funding for program shall not exceed \$100,000,000 from amount otherwise appropriated.

## Sec. 3 – Pilot Program on Improved Access for Veterans.

- (a) Establishing pilot program
  - (1) Requires the Secretary of Veterans to establish a pilot program within 180 days of enactment of this Act to improve access to certain telehealth services for veterans.
  - (2) Requires the Secretary select not fewer than five facilities of the Department of Veterans Affairs, not fewer than three shall serve rural or highly rural areas and provide (see: *Tests Covered*).
  - (3) Requires veterans eligible for the program apply as the Secretary determines appropriate and establishes program eligibility requirements for veterans seeking to apply to the program.
  - (4) Program participants will not be charged for any cost of services furnished under the program.
  - (5) The program shall last three years after it commences and may be extended for up to two years.

## (b) Reports

- (1) Requires not later than one year after the pilot program commences to have interim report
- (2) A final report is due not later than 90 days after termination of the pilot program.

# (C) Definitions

- (1) Appropriate Congressional Committee the term "appropriate congressional committee" means the Committee on Energy and commerce, the Committee on Veterans' Affairs, and the Committee on Ways and Mean; it also includes the Senate Committee on Health, Education, Labor, and Pensions and the Committee on Veterans' Affairs of the Senate.
- (2) Assistive Telehealth Consultation The term "assistive telehealth consultation" has the meaning given such term as added by Section 1 of this Act.

#### **Tests Covered:**

- Medical devices (as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act or wearable patient monitoring device, including adaptive artificial intelligence, machine learning, software as a medical device (SaMD) technologies that operate to the full scope of their purpose as defined by the FDA and are identified by the Secretary as having appropriate home use; and
- Are either a test for the diagnosis of influenza or similar respiratory condition and is required to diagnose COVID-19, or a test ordered in conjunction with a COVID-19 test to discount a diagnosis of influenza or related diagnosis. This test could also be a serology test for COVID-19; and
- Other tests include those for the diagnosis of prostate cancer, ovarian cancer, breast cancer, hypothyroidism, rheumatoid arthritis, celiac disease, vascular inflammation, cardiovascular health, strep throat, lipoprotein (A), haptoglobin test, prediabetes and diabetes screening, IgE allergy tests, a screening or diagnostic capsule endoscopy; or any other test identified by the Secretary that is approved and considered appropriate for home use.